

Minutes and Actions for Biologics Subteam Discussion (November 20, 2008)

Attendees:

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WIKI Link: <http://spl-work-group.wikispaces.com/Biologics>

Minutes:

Highlights of the CBER 1-day Workshop (November 17, 2008) [M Glavin pulled most of this section together – Thanks!]

- FDA is currently finalizing the Final Rule and Guidance for SPL Electronic Establishment Registration and Drug Listing. No release date yet.
- FDA/CBER will assume that UNILs supplied in their letters are correct if they do not hear from sponsors within 15 days after receipt of the letter. Sponsors MUST reply to the named contact promptly if more than 15 days will be needed to verify the descriptions used to determine the UNILs. The descriptions that will be provided in the letters were pulled from PI & BLA if needed. Requests for changes to UNILs require a Level 2 STN response.
- Sponsors may sign up for monthly email updates of controlled terminology at: www.fda.gov/oc/datacouncil . This site has information on many of the vocabularies used by the FDA.
- FDA/CBER suggested waiting to submit SPL associated with a CBE until the sponsor was sure that submission was accepted as a CBE in case the Agency reassigns the submission to a Prior Approval.
- FDA is testing a Word conversion tool which could eliminate the requirement to send content of labeling in Word.
- The Import Division staff are getting training on electronic listing. This training should reduce requests for paper documentation at site audits, Customs.
- SPL Validation notes
 - The **version #** will be assigned by the company (not to be confused with the id or setid).
 - The **effective date** should be the (approximate) date of the submission. Whenever SPL fails validation at FDA, an error report will be sent to sponsor who will correct the file & resubmit using the same id # and version #. Once the SPL file has been successfully processed by FDA, any correction to SPL requires a new id # and new version #. Setid never changes.
 - SPL may fail validation at FDA for even an extra space after the sponsor telephone # but FDA's error report will provide detailed

list of all reasons document fails. Error report would be returned to sponsor within 24-48 hours. If it validates, it will be sent on to NML & posted.

- Listing of certain data elements including **inactive ingredients** (i.e., trace amounts or propriety ingredients) may be marked as confidential in which case FDA will “hide” them public posting on Daily Med.
- Enter the “**Marketing Date**” with on or off for ‘status’, date you want SPL transmitted to NML for ‘start marketing date’, and end of expiry date for a discontinued item for ‘end marketing date’.
- Enter the “**Market Category**” with either BLA or NDA for ‘category’ and # for ‘application’.
- New field: (product image) for images provided by the National Institutes of Health(NIH)’s National Library of Medicine (NLM). This is not a field for sponsor-provided photographs of products. These images would be part of the DailyMed view.
- FDA is working with US and international standards groups (ISO) to create globally usable product terminology. The UNII codes for SPL are currently used only in the United States.
- Use the Electronic Submissions gateway – it is required for any electronic listing submission after May 31, 2009

Debrief on Content of Label Submissions

- No specific issues raised about newly submitted content-of-label SPL. #1 question – can I submit SPL to the application without UNII codes for the active ingredient(s). Yes for draft SPL. Final SPL cannot be posted to Daily Med without the UNII codes

UNII Codes for CBER Active Ingredients

- Sponsor communications containing UNII codes for currently active products are being mailed in batches. Alert your regulatory representation to be ‘on the lookout’ for letters, as they are targeted for mailing in 2008.

[REMINDER] Submission of SPL Content of Labeling

- SPL must be submitted with relevant CBER applications (BLA, sBLA, CBE, Annual Report) starting October 15, 2008.
- For the first 12 months of CBER content-of-labeling SPL submission: include SPL with Annual Report – even if there have not been changes. This will result in all relevant products having SPL on file at the FDA within one year after implementation. Consult your Reviewer if there may be a delay in submitting an SPL.
- Draft SPL will be reviewed whether or not it has all UNII codes. If the codes are available, fill them in, as this facilitates the review process.
- Final SPL will not pass validation without UNII codes. It will not be posted on the DailyMed site without them.

- For eCTD submissions, SPL is placed in Module 1, section 14 (Labeling) in Draft Labeling or Final Labeling as appropriate. If review aids such as the Vaccine Hierarchy worksheet or equivalent are included, place them in Module 1 as well.
- For other electronic submissions, make sure that the SPL content of labeling files are in their own \SPL folder. This folder must contain the *.xml file and any accompanying figures.
- Drug Listing and Establishment Registration SPL is required starting June 1, 2009. Prior to that, sponsors are being encouraged to submit these SPL through the Voluntary Pilot Program.

Actions:

All Sponsor Reps:

If you are submitting SPL with upcoming CBER submissions for new, not-yet-approved products, and need UNII codes for your ingredients, alert the Review Division that UNII assignments are needed for one or more active ingredients and moieties.

Sponsor Reps with Immune Globulin products:

Take a look at the worksheet and identify how your product(s) would be characterized.

Next Meeting: January 2009.